DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 19, 2016

Ambicare Health Ltd.
c/o Susan D'Arcy
iSMART Marketing Services Ltd.
129 Green Lanes, Wylde Green, Sutton Coldfield,
Birmingham, GB B735LT West Midlands

Re: K143713
Trade/Device Name: Lustre PRO Light System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 15, 2015
Received: November 23, 2015

Dear Ms. D'Arcy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143713

Device Name
Lustre PRO Light System

Indications for Use *(Describe)*
The Lustre PRO light system is indicated for the treatment of mild to moderate acne.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Alba Innovation Centre
Alba Campus
Livingston
EH54 7GA
Scotland
United Kingdom

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

Submitter's Name:

Ambicare Health Ltd

Submitter's Address:

Ambicare Health Ltd
10 Lochside Place,
Edinburgh,
EH12 9RG
Scotland,
UK

SBDN: SBD158325

User Fee Organisation Number: 297701

Establishment Registration Number:

Still to be established

Contact Person:

Susan D'Arcy

Telephone +44 (0) 7880313315

Date Prepared: December 16th 2014

Date Modified: May 30th 2015

November 13th 2015

Device Trade Name:

Lustre PRO Light System

Device Common Name:

Lustre Pure Light system

Device Classification Information:

Regulation Number	Device	Device Class	Product Code	Classification Panel
21 CFR 878.4810	Over the counter powered light based laser for Acne, 21 CFR 878.4810	Class 2	OLP	General & Plastic Surgery

Predicate devices

The Ambicare Health, Lustre PRO Light system is substantially equivalent to the Silk'n Blue (K121435) (Home skin innovations).

Device Description:

The Lustre PRO light system is a small portable non-invasive device, comprising of a rechargeable controller and therapy heads containing light emitting diodes, emitting blue light at a peak wavelength of 415nm, and a Full Width Half Maximum (FWHM) of 15nm.
The therapy heads are designed to be attached to the skin at the site of the acne using a disposable polyethylene film impregnated with a medical-grade adhesive. The controller comprises of an LCD graphical user interface, 3 control buttons, a coaxial connector and 3 mini USB connectors. The controller switches the therapy heads on and off and includes a programmable timer, allowing modification of treatment time and indicators for battery level, therapy head status and treatment time remaining. The device contains sensors which monitor the therapy heads and emit audible and visible alarms relating to overheating and disconnection of the therapy heads.

Intended/ Indications Use:

The Lustre PRO light system is indicated for the treatment of mild to moderate acne.

.

Technological Characteristics:

A comparative review of the Lustre PRO Light System with the predicate devices found that the technologies, mode of operation, and general principles for treatment with this device were substantially equivalent to the predicate device.

Substantial Equivalence:

The Lustre PRO and Silk'n Blue are phototherapy devices that use non thermal blue light energy and are intended for the treatment of mild to moderate acne. They both use identical wavelengths and have identical light outputs. The technological characteristics of the Lustre PRO Light System are similar to the technological characteristics of the listed predicate device. Where there are differences between the Lustre PRO Light System and the predicate device these differences have been negated by non-clinical performance testing. The Lustre PRO light system raises no new questions of safety and efficacy and introduce no new risks.

Non Clinical Performance & Safety Data:

The Lustre PRO Light system complies with IEC 60601-1: "Medical Electrical Equipment Part 1 - General Requirements for Basic Safety and essential performance" IEC/EN 60601-1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and test.

The Lustre Pure Light System has been evaluated against EN62471:Photobiological Safety of Lamps and Lamp Systems" in consideration of maximum possible light exposure to users and the results demonstrate that it poses no risk of retinal injury due to either the blue-light phototoxic effect, or the thermal damage mechanism.

Lustre Pure Light System was assessed with regards to usability for compliance with IEC 62366: Medical devices - Application of usability engineering to medical devices and design verification for compliance with IEC 60601-1-11: General requirements for basic safety and essential performance - Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

In addition, testing and analysis of the adhesive strips have demonstrated compliance to ISO 10993: Biological evaluation of medical devices.

A self-selection and usability study of 71 subjects demonstrated that the labelling and user guide for the Lustre PRO system exceeded comprehension levels determined a priori and demonstrated that the device could be used safely and effectively by lay persons.

Data generated from post market clinical experience does not generate any significant doubts to the similarity of the Lustre acne system to other commercial and clinically tested Blue LED light systems. The data presented is suitable to be able to justify safety and performance of the device in relation to predicate devices with similar technology.

These non-clinical tests demonstrate that the Lustre PRO light system is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate devices.